Docket No.: TJU0006-101 Serial Number: 10/695,578 PATENT Filed: 10/27/2003

## REMARKS

#### **Status of the Claims**

Claims 24-46 are pending in the application.

Claims 24-46 have been rejected.

By way of this amendment, claims 24-29 and 36-39 have been canceled.

Upon entry of this amendment, claims 24-46 will be pending.

# **Summary of the Amendment**

Claims 24-29 and 36-39 have been amended to change the term ""ST receptor" to the more conventional and scientifically used term "guanylyl cyclase C." Those skilled in the art would readily appreciate that the two terms are interchangeable. Support is found on page 7 of the specification. No new matter has been added.

# Rejection under 35 U.S.C. §112, second paragraph

Claims 24-46 have been rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as his invention.

It is asserted that reference to "ST receptor protein" in the claims renders them indefinite. Applicants have amended claims 24-29 and 36-39 to delete the term "ST receptor" in favor of the more conventional and scientifically used term "guanylyl cyclase C." Those skilled in the art would readily appreciate that the two terms are interchangeable. Moreover, those skilled in the art would readily know the metes and bounds of claim based upon the reference to guanylyl cyclase C, a well known protein having specific structure and function.

The claims as amended are clear and definite. Applicant respectfully requests that the rejection of claims 24-46 under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as his invention be withdrawn.

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# Rejection under 35 U.S.C. §112, first paragraph Written Description Rejection

Claims 24-46 have been rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. It is asserted that the subject matter in the claims is not disclosed in the specification in such a way to reasonably convey to those skilled in the art that the inventors, at the time of the invention, had possession of the claimed invention. It is asserted that the claims refer to ST receptors and the specification discloses only a single sequence for ST receptors. Applicant respectfully disagrees.

As noted above, the claims have been amended to refer to "guanylyl cyclase C" instead of "ST receptor." Those skilled in the art would readily appreciate that the two terms are interchangeable. Nevertheless, guanylyl cyclase C, is the more common term for this well known protein which has a specific structure and function. No sequence information is required to describe guanylyl cyclase C in order to convey the scope of term as used in the claims.

Applicant respectfully urges that the claims are in compliance with the written description requirement. Applicant respectfully requests that the rejection of claims 24-46 under 35 U.S.C. §112, first paragraph, be withdrawn.

## **Enablement Rejection**

Claims 24-46 have been rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the enablement requirement. It is asserted that the claims contain subject matter which was not described in the specification in such a way as to enable those skilled in the art to which it pertains or with which it is most nearly connected, to make and/or use the invention.

Provided herewith is an unexecuted declaration of the inventor, Dr. Scott Waldman, reporting results from his lab which demonstrate that the claimed invention is operable in animal models. An executed copy will be provided to the Office. The declaration states that

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administration of protein comprising GCC extracellular domain induced robust antigenspecific T cell responses. The declaration also states that administration of an adenovirus vector construct which expresses the extracellular domain of guanylyl cyclase C was effective *in vivo* in tumor challenge models. The declaration provides evidence that the claimed invention is enabled by the specification.

The claims are in compliance with the enablement requirement of the first paragraph of 35 U.S.C. §112. Applicant respectfully requests that the rejection of claims 24-46 under 35 U.S.C. §112, first paragraph, as failing to comply with the enablement requirement be withdrawn.

#### Conclusion

Claims 24-46 are in allowable form. The examination of claims 24-46 and passage to allowance are respectfully requested. An early Notice of Allowance is therefore earnestly solicited. Applicants invite the Examiner to contact the undersigned attorney at 215.665.5592 to clarify any unresolved issues raised by this response.

As indicated on the transmittal accompanying this response, the Commissioner is hereby authorized to charge any debit or credit any overpayment to Deposit Account No. 50-1275.

Respectfully submitted,

/Mark DeLuca/ Mark DeLuca, Reg. No. 33,229

Date: February 27, 2007 COZEN O'CONNOR, P.C.

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Attachment: Unexecuted Declaration of Scott Waldman